REMARKS

I. Nationalization

This application represents the U.S. national stage under 35 U.S.C. § 371 of International Patent Application PCT/AU2004/000253, filed February 27, 2004, which claims priority to Australian Application Serial No. 2003900927, filed February 28, 2003.

Although the text of the International Application was transmitted to the U.S. receiving office from the International Bureau, as a precaution under 35 U.S.C. § 371(c)(2), an additional copy is enclosed herewith in the form of the published PCT Application WO 2004/076423.

II. Amendments to the Specification

An amendment is made to page 1 of the specification to insert the claims for priority. Amendments are made at pages 6 and 7 of the specification to correct certain oversights, which also match the amendments to claim 13 (see below). A single paragraph abstract is also provided as a separate page by amendment. These amendments to the specification comply with the revisions to 37 C.F.R. § 1.121 and no new matter is encompassed by the amendments to the specification.

The corrections to claim 13 and pages 6 and 7 of the specification are proper under PCT rules, and such amendments were entered during examination of the PCT application to address the comments in Section VIII of the Written Opinion (copies of Written Opinion and response filed September 13, 2004 enclosed). These amendments are also proper under U.S. statutes and case law, as the same reasoning applies. In particular, that one of ordinary skill in the art would not only recognize the existence of the errors in the specification, but would also appreciate the appropriate correction. *In re Oda*, 170 USPQ 268 (CCPA 1971). See also, MPEP 2163.07,

describing amendments that are NOT new matter (emphasis as in original; MPEP, February 2003, page 2100-177, column 2). Therefore, the amendments to the specification and claim 13 do not constitute new matter.

III. National Stage Claims

After according a U.S. filing date, and **before** calculating the filing fee, entry of the foregoing claim amendments is respectfully requested.

The original, unamended claims in the PCT application, as published in WO 2004/076423, form the basis for the amendments introduced herein.

As the claims in the PCT application were drafted with multiple dependencies and certain first and second medical use claims, Applicants have revised the claims to better accord with U.S. practice and to place the application in form for U.S. examination. The changes to the claims are being made to achieve these objectives, thereby also reducing the filing fee. The submission of the present claims does not represent abandonment of any of the subject matter of the claims in the PCT application. Indeed, the present claims are fully supported by the claims in the PCT application, as well as by the specification and claims of the PCT and priority application, and the new claims do not in any way constitute new matter.

IV. Status of the Claims

The PCT application was filed with claims 1-25. PCT examination indicated each of claims 1-25 to have unity of invention, which should be noted upon entry into the U.S. national stage. After the Written Opinion, claim 13 was amended on September 13, 2004 to correct oversights in claim drafting. Thus, at the time of the International Preliminary Examination Report (IPER), claim 13 in the PCT application had been amended.

According to the revisions to 37 C.F.R. § 1.121, entry into the U.S. national stage should account for the changes to the claims since the designation of the U.S. Therefore, prior to entry into the national stage, claims 1-25 were pending. Presently, claims 1, 2, 5, 6, 8-16, 23, 24 and 25 have been amended without prejudice or disclaimer, and now better accord with U.S. practice. Claims 17-22 have been canceled without prejudice or disclaimer, as not complying with U.S. requirements. No claims have been added.

Claims 1-16 and 23-25 are therefore in the case. According to the revisions to 37 C.F.R. § 1.121(c), a copy of the pending claims is provided in the amendment section.

V. Support for the Claims and Specification

The revisions to the claims are being made to better accord with U.S. practice, to reduce the filing fee, correct oversights in claim 13 and to reflect certain aspects of the invention in the PCT application. The present claims are fully supported by the claims in the PCT application, in addition to the specification.

Claim 1 has been revised so that the body better matches the preamble, in further accord with U.S. practice.

Claim 2 has been revised to reflect only one of the original two embodiments, in better accord with U.S. practice.

Claim 5 has been revised to further limit only one of the alternatives in claim 4, in better accord with U.S. practice.

Claims 6, 8, 9, 10, 11 and 12 have each been revised to be singly dependent.

Claim 13 has been revised to be singly dependent and to correct oversights in claim drafting, as supported by the specification as filed. The corrections to claim 13 and pages 6 and 7

of the specification match those entered during examination of the PCT application to address the comments in Section VIII of the Written Opinion (copies of Written Opinion and response filed September 13, 2004 enclosed).

Claim 14 has been revised to reflect the second embodiment originally in claim 2.

Claim 15 has been revised to reflect the second category of embodiments originally in claim 5.

Claim 16 has been revised to reflect the second embodiment originally in claim 10.

Claim 23 has been revised to be an independent claim, as in original claim 22, and to recite certain particular carriers.

Claim 24 has been revised to provide an additional independent claim based upon claims 1, 4 and 5.

Finally, claim 25 has been revised to provide an additional dependent claim, as originally represented in claim 5.

It will therefore be understood that no new matter is encompassed by any of the amended claims.

VI. Patentability

The International Preliminary Examination Report (IPER) (copy enclosed) issued for the PCT application established unity of invention for all PCT claims. The present claims, which represent a sub-set of the claims in the PCT application, revised to better accord with U.S. practice, are therefore drawn to a unified invention for the purposes of examination in the U.S.

Importantly, the IPER also indicated both novelty and inventive step for each of PCT claims 1-25. The present U.S. claims are derived from PCT claims 1-25, revised to better accord

with U.S. practice and with the first and second medical use claims being canceled as drawn to non-statutory subject matter. The present U.S. claims are thus directed to subject matter determined to be novel and inventive during PCT examination, as set forth in the IPER. This is compelling evidence that the U.S. claims also define a novel and non-obvious invention. In light of the positive IPER, Applicants therefore respectfully request an early indication of allowance for the present application.

In addition, the repeat poultry trial for "Iksin", a compound of the claimed invention, described in the specification at Example 2 has now been successfully completed. The results from giving birds feed alone, feed supplemented with Iksin (referred to as "BDM-I") and feed supplemented with another well-used feed supplement, zinc Bacitracin, are attached as **Exhibit A**. The data from these controlled studies show that, although weight gain was the same in all three groups, birds given Iksin (BDM-I) achieved the same weight gain with a 9.2% reduction in mean feed intake compared to untreated controls ($P = 0.003$), whereas birds given zinc Bacitracin showed a 2.9% reduction ($P = 0.02$). Thus, Iksin (BDM-I) was over 200% better than the positive control, zinc Bacitracin, in reducing feed intake ($P = 0.02$).

The data in **Exhibit A** also show that Iksin (BDM-I) induced a significantly improved feed conversion ratio, with a 6.8% reduction over untreated controls ($P = 0.008$), compared to a 4% reduction by zinc Bacitracin ($P = 0.08$). Thus, in terms of feed conversion ratio, Iksin (BDM-I) out-performs the positive control by 2.8%. This translates to a saving of 5 tonnes of feed per 50,000 bird broiler shed per growing cycle (approximately 6-7 weeks), which in turn equates to a saving of 30 tonnes of feed per annum per shed. In Australia alone (the location of

the inventors), there are approximately 6,500 of such broiler sheds, resulting in a saving of 195,000 tonnes of feed per annum for raising chickens in Australia.

Applicants would also like to note the following information relating to broiler sheds in the United States:

- Chicken meat production in the United States in 1999, the latest available figures, was 13.6 million metric tons.
- It takes an average of 1.7 kgs of feed to produce 1 kg of chicken meat body weight.
- Therefore, 1.7 × 13.6 = 23 million metric tons of feed required to produce 13.6 million metric tons of chicken meat.
- The 6.8% reduction in feed intake following the use of BDM-1 equates to a savings of 1.5 million metric tons of feed per year in the United States.

VII. Fees and Formalities

The national filing fee and claim fees are included herewith. The fees have been calculated according to the new fee schedule and **after** the present changes to remove the multiple dependencies in the claims. Any omitted fees should be deducted from Williams, Morgan & Amerson, P.C. Deposit Account No. 50-0786/4050.003200. Applicants' U.S. representatives have been advised that Applicants are entitled to pay small entity fees, and a verified statement to this effect is no longer required.

As further precautions for the U.S. application, additional versions of the formal drawings are presently enclosed. The executed formal documents and any procedural requirements

deemed necessary by the Office will be completed in due course. Should the Office have any questions, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

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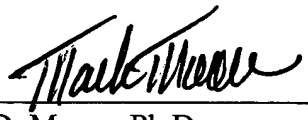

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